PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
VAS-5511A1		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 00/ 26239	25/09/2000	23/09/1999
Applicant		
EDWARDS LIFESCIENCES CORPORATION et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [X] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 5

   [ ] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [X] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
T/US 00/26239

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 37242 A (ANSON MEDICAL LTD ;BEATON GAIL (GB); BUTCHER PETER (GB); MCLEOD AL) 29 July 1999 (1999-07-29) page 24, last paragraph -page 25, paragraph 1; claim 25; figures page 27, paragraph 2	1-3, 8-12,15, 19
A	---	4-7,13, 14,16
X	EP 0 808 614 A (SAMSUNG ELECTRONICS CO LTD) 26 November 1997 (1997-11-26) page 2, line 31 - line 45; figures	1-3,10
A	---	19
X	WO 99 32050 A (EMBOL X INC) 1 July 1999 (1999-07-01) figures 3,8-13	1,19
A	---	2,3
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 June 2001	12/06/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
[redacted]T/US 00/26239

C.(Continuation) DOCUMENTS CONSI[redacted]ED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 01073 A (MEDTRONIC INC) 14 January 1999 (1999-01-14) page 10, line 11 -page 11, line 32; figure 7 -----	17,18

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
[redacted]/US 00/26239

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9937242	A	29-07-1999	AU	2288699 A	09-08-1999
			BR	9907209 A	03-10-2000
			EP	1049420 A	08-11-2000
			GB	2349827 A	15-11-2000
EP 0808614	A	26-11-1997	KR	170220 B	20-03-1999
			KR	170219 B	20-03-1999
			CN	1170612 A	21-01-1998
			JP	10043315 A	17-02-1998
			US	6027525 A	22-02-2000
WO 9932050	A	01-07-1999	AU	1937499 A	12-07-1999
			EP	1041940 A	11-10-2000
WO 9901073	A	14-01-1999	US	6097978 A	01-08-2000

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Published:
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(54) Title: PRE-SHAPED INTRALUMINAL GRAFT

(57) Abstract: An intraluminal graft having a predetermined substantially a linear configuration is ideally fitted within individuated aneurysmal regions, tortuous or primarily non-linear vessels, and a method of emplacing the same likewise discloses novel aspects.

WO 01/30270 A2

PRE-SHAPED INTRALUMINAL GRAFT

This application claims all Paris Convention Priority rights from Australian Provisional Patent Application No. PQ3029, filed 23 September 1999.

Field of the Invention

The present invention relates to an intraluminal device for use in the treatment of aneurysmal or stenotic disease. Particularly, the present invention relates to endovascular emplacement of structures designed to enhance a patient's vasculature, for example through the extension of ostensively aneurysmal growths, dissections or related issues.

Background of the Invention

Endovascular grafts and stented grafts are generally known to be useful in several distinct configurations. For example, it is known to use intraluminal grafts and stents of various designs for the treatment of aneurysms such as aortic aneurysms, and occlusive diseases affecting the vasculature or other vessels comprising, inter alia, the hepato-biliary and genito-urinary tracts (which are all hereinafter "vessels"). It is known to form such an intraluminal device of a sleeve in which is disposed a plurality of wire stents (see Balko A. et al (1986) *Transfemoral Placement of Intraluminal Polyurethane Prosthesis for Abdominal Aortic Aneurysms,* 40 Journal of Surgical Research 305-309; Mirich D. et al. (1989) *Percutaneously Placed Endovascular Grafts for Aortic Aneurysms: Feasibility Study* 170(3) Radiology 1033-1037).

In the past, such devices have commonly been used in the treatment of, or to exclude aneurysms, *see* United States Letters Patent No's. 5,782,904; 5,968,068; 6,013,092; 6,024,729; 6,045,557; 6,071,307; 6,099,558; 6,106,540 and 6,110,191 each of which is licensed or assigned to and may be available from

Edwards Lifesciences LLC (Orange County, California), the instant assignee, and each of which is expressly incorporated herein by reference.

Whatever the purpose for which an intraluminal device is being used, it has the capacity to be inserted percutaneously through a distal (or proximal) and connecting vessel to that in which the device is to be used, for example, through the femoral artery in a catheter, where the device is intended to be used in the treatment of a lesion within the aorta. Upon release of the device from the catheter it may expand to a desirable size, and may extend above and below the lesion thereby bridging the lesion. This method of inserting the device into the body of a patient is applicable where the invention is used in the treatment of aneurysmal disease or stenotic disease.

There are several potential problems associated with most known intraluminal devices. For instance, conventional grafts are not designed to follow the natural curvature of some vessels and may, therefore, kink if required to bridge a section of vessel that has a natural curvature.

Likewise, pursuant to use in particularly tortuous -or specifically diseased vessels – it is often necessary to have "taylor-made" or individually altered/modified grafts on the basis of whether an aortobi-iliac or aorto Uni-iliac emplacement is indicated.

Further to such natural curvature of a vessel, there may also be pathological curvature associated with aneurysmal disease. For example it is known that as an aneurysm situated in, for example, the aorto-iliac region expands, it can cause the artery to deviate in a direction towards the extending aneurysmal sac. This in turn may cause the vessel to shorten in length across this section of artery which may sometimes result in displacement or kinking of any intraluminal device positioned in the artery. Known devices ostensively ignore these types of individuated needs, and have heretofore neither addressed nor ameliorated the majority of the most pressing concerns and issues.

The present invention is directed to an alternative form of intraluminal device which is designed to overcome the above problems, inter alia.

Summary of the Invention

In a first aspect, the present invention consists in an intraluminal device comprising a tubular body having a length, a first end and at least one second end, wherein the tubular body has a pre-determined non-linear shape, the pre-determined shape corresponding with the shape of a non-linear shaped portion of a vessel in which the device is to be disposed.

In one embodiment the tubular body is curved along its length between the first and the at least one second end.

In a further embodiment, the tubular body forms an S-shape along its length between the first and at least one second end.

In another embodiment, the intraluminal device is a graft for bridging an aneurysm in an artery of a patient.

In a still further embodiment of the invention, when the intraluminal device is in situ within a vessel of a patient, the tubular body is configured such that it is curved along its length in an anterior-posterior plane.

In yet a further embodiment, when the intraluminal device is in situ within a vessel of a patient, the tubular body is configured such that it is curved along its length in a lateral plane.

In another embodiment, when the intraluminal device is in situ within the vessel of a patient, the tubular body is configured such that it is curved along its length in both an anterior-posterior and a lateral plane.

In a preferred embodiment, the length of the tubular graft body is made from a single piece of material that has been cut as such an angle so as to facilitate the curvature of the tubular graft body.

In a further embodiment, the first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater that the reminder of the first end.

In a still further embodiment of the invention, the shape of the vessel or vessel portion in which the device is to be disposed may be pre-determined and the device chosen or specifically manufactured such that the shape of the device corresponds with the shape of the vessel or vessel portion. The shape of the vessel or vessel portion may, in preferred embodiment, be determined by either ultrasound, plain abdominal films or by CT scanning. In this manner, the device is custom made from imaging of the vessel or vessel portion such that it fits securely within the vessel or vessel portion.

In a second aspect, the present invention consists in an intraluminal device comprising a tubular graft body having a length, a first end and at least one second end wherein the first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater that the remainder of the first end.

This has the advantage that when the device is disposed in a curved vessel, the first end of the tubular body continues to abut against the wall of the vessel in which the device is disposed even when the vessel deviates from its normal path due to pathological changes in the vessel or if the vessel has a natural curvature. Because the angled first end of the tubular body continues to abut against the surrounding wall of a vessel around substantially its entire periphery it forms a tight seal thereby reducing the likelihood of displacement of the device due to pathological deviation of a vessel from its normal path or due to the natural curvature of a vessel.

In a third aspect, the invention relates to the method for positioning an intraluminal device according to the first or second aspects of the invention, including the steps of introducing a catheter or other delivery device into a vein, artery or other vessel in the body of a patient when the device body is in a radially compressed state; causing the intraluminal device to be moved through the catheter or other delivery device until the intraluminal device extends into the vessel from a proximal end of the catheter or other delivery device; causing or allowing the itraluminal device to expand; and withdrawing the catheter or other

delivery device along with any other apparatus used to introduce the intraluminal device into the vessel.

In one embodiment, the device is adapted such that it can be brought to a substantially straight configuration along its length and radially compressed to fit internal the catheter or other delivery device. The device is moved through the catheter or other delivery device until it extends from the proximal end of the catheter or other delivery device whereupon the device expands and takes on its pre-determined curved configuration.

In a further embodiment, the catheter may be configured such that it is slightly curved along its length. The catheter may be configured such that it is curved along its length in either an anterior-posterior plane or a lateral plan or in both planes.

The intraluminal device according to this invention may be used in the treatment of aneurysms or stenotic disease. In addition to treating aortic aneurysms the device is particularly suitable for treating aneurysms of the femoral artery, the popliteal artery, the thoracic segment of the aorta, visceral arteries such as the renal and mesenteric arteries, the iliac artery and the sub-clavian artery. Further, in addition to the treatment of stenotic lesions in the peripheral vasculature, the invention may be used in the treatment of, inter alia, vessels comprising the coronary circulation. However the application of the invention for use in the treatment of stenotic disease is not to be understood as limited to the vascular system only, the device may be used to treat stenotic lesions in other vessels including, for example, those comprising the hepato-biliary and genito-urinary tracts.

In cases where the invention is to be used for the treatment of aneurysmal disease, the tubular device body is preferably formed of a thin biocompatible material such as Dacron™ or polytetrafluoroethylene (PTFE). The tube material is preferably crimped along its length to increase the flexibility of the device, however, uncrimped material may be used in suitable circumstances. In preferred embodiments of the invention for use in the treatment of aneurysmal disease, the

device body may be formed from a material having a limited amount of diametric elasticity to ensure that it can be expanded into contact with the vessel wall, forming a seal between the wall of the device and the wall of the vessel such that the escape of the vessel contents into the aneurysmal sac is prevented.

In addition, in a further preferred embodiment, the device of all three aspects of the invention includes a stent or a series of spaced apart stents which forms a framework to which may be attached an endoluminal graft. The framework of the device body may be circumferentially reinforced along its length by a plurality of separate, spaced-apart, malleable wires. Each of such wires can have a generally closed sinusoidal or zig-zag shape. The wires are preferably formed of stainless steel or another metal or a plastic which is malleable and is biocompatible. If the device is adapted such that it is substantially straight along its length to facilitate packaging within a catheter, the wires may be made from Nitinol™ or other such shape memory or heat sensitive material such that when the device is in situ within a vessel, the temperature in the vessel causes the material to take on a pre-determined configuration. The pre-determined configuration of the material in this embodiment causes the device to adopt a pre-determined curved configuration.

Each wire is preferably woven into the fabric of the device body to integrate the body and the reinforcing wires. This prevents any possibility of the wire reinforcement separating from the device body during introduction of the device or throughout its life. If the device body is of a woven material the wires may be interwoven with the device body after its manufacturer. If the device body is not woven but is knitted or of an impervious sheet material then the wires may be threaded through suitable holes formed in the device body. Alternatively the stent or stents may be continuous and may be on the radially inner or the radially outer side of the graft wall. In either case expansion of the graft or grafts will cause the graft to expand and press against the wall of the vessel into which the device has been placed. In one particular embodiment of the second aspect of

the invention, the wires are adapted such that substantially the entire periphery of the angled one end of the tubular body is reinforced.

The tubular graft body may be of the self-expandable type wherein the wires are made from a shape memory or heat sensitive material. In this embodiment, the tubular graft body is ejected from the proximal end of the catheter and into the target vessel. Once in the vessel, the tubular graft body takes on its pre-determined shape. Alternatively, the tubular graft body may be compressed within the lumen of a catheter such that upon release of the tubular graft body from the proximal end of a catheter and into the target vessel, the tubular graft body springs into its pre-determined shape. In a further embodiment, the expansion of the tubular graft body within the target vessel may be aided by way of a balloon which, when inflated pushes the tubular graft body towards the wall of the target vessel.

In addition to or instead of being circumferentially reinforced, the tubular graft body may be longitudinally reinforced. In one embodiment, a longitudinally reinforcing wired may be connected to one or more circumferentially reinforcing wires. The advantage of longitudinal reinforcement is that the tubular graft body is less likely to compress along its length during placement of the tubular graft body in the target vessel, resulting in a concertina affect.

In a still further embodiment the device of the invention is typically substantially of constant diameter along its length, that is, it is substantially cylindrical or may in some instances be frusto-conical in shape with a diameter that increases or decreases along the length of the device.

In another embodiment, the device of the invention is adapted to bridge an aneurysm that extends up to or slightly beyond an arterial bifurcation. In such a case the device is a graft which has a bifurcation at its downstream end, a so-called "trouser graft", and may be placed wholly within the primary artery. A supplemental graft may then be introduced through subsidiary arteries and overlapped with the lumen of the bifurcated part of the primary graft. In the case

of an aneurysm in the aorta, for instance, that extended into each of the common iliac arteries the primary graft would be placed in the aorta. Supplemental grafts which dock with the bifurcated end of the primary graft would then be inserted through each of the common iliac arteries.

Brief Description of the Drawings

One preferred embodiment of the invention is now described with reference to the accompanying drawings in which:

Figure 1 is a diagrammatic partially cut-away ventral view of a patient with an aortic aneurysm which has been bridged by a device according to the present invention.

Figure 2 is a simplified view of a device according to the prior art.

Figure 3 is a simplified view of a device according to the present invention.

Figure 4 is a detailed longitudinal view of an aortic aneurysm that is bridged by a device according to the prior art.

Figure 5 is a detailed longitudinal view of an aortic aneurysm that is bridged by the device of the present invention.

Figure 6 is a side elevational view of an aortic aneurysm that is bridged by a device according to the prior art.

Figure 7 is a side elevation view of an aortic aneurysm that is bridged by the device of the present invention.

Figures 8a and 8b are representations of a delivery mechanism of one embodiment of the invention.

Figure 9 likewise illustrates an alternate embodiment of a graft to be emplaced and implanted according to the teaching of the present invention.

Referring now to Figure 9, an alternate preferred embodiment shows a self-expanding or balloon expandable graft utilizing, for example, a Dacron graft. According to the instant teachings a graft may be secured to a desired portion of

the aorta and iliac arteries by use of the self expanding radial force of wireforms attached to the dacron graft.

According to this teaching, a graft having at least 28mm of trunk includes a tapered portion. Balloon attachment or self-expansion may be used according to this alternate embodiment, as discussed above and claimed below.

Best Mode of Carrying Out The Invention

The present inventors have come up with novel ways to enhance the human vasculature by means of grafts which have an alternate, and substantially "pre-formed" shape for certain applications. Unlike known systems, particularly difficult anatomical structures may be ameliorated according to the instant teachings.

An endovascular graft according to the present invention is generally shown as 10 in the drawings. The endovascular graft 10 is adapted for insertion transfemorally into a patient to achieve bridging and occlusion of an aneurysm 11 present in an aorta 12. It is to be understood that the present invention has a wider applicability and could be utilized in vessels other than the aorta. As is shown in Figure 1 the aorta 12 bifurcates to form the common iliac arteries 13 which subsequently divide into the external 14 and internal 15 iliac arteries, the external iliac artery 14 eventually becoming the femoral artery 16. The aortic aneurysm is located between the renal arteries 17 and 18 and the junctions of the bifurcation of the aorta 12 into the common iliac arteries 13. The graft 10 is inserted inside a catheter 9 and introduced into one of the femoral arteries 16 of a patient. Once the catheter 9 is located appropriately with its proximal end in the aorta 12 the graft 10 is ejected from the catheter and expanded so that each end 19 and 21 is in intimated contact around its full periphery with the aorta 12. The graft 10 then bridges the aneurysm 11 and isolates any thrombosis or gelatinous

material associated with the aneurysm outside the graft 10 to reduce the risk of embolisation.

The endovascular graft 10 comprises a tube 22 of woven Dacron™. The tube is reinforced along its length with a plurality of separate spaced apart wires that are interwoven in the Dacron™. Between the two ends 19 and 21 the body of the tube 22 curves in a manner that enables the graft 10 to follow the natural or pathological contours of the aorta.

Figures 2 and 3 indicate the difference between the graft of the present invention 10 and conventionally used grafts 23. The conventionally used grafts 23 are substantially straight in design and do not account for either natural curvature of an artery or pathological curvature due to the ballooning and pulling effect of an aneurysm 11. Accordingly, when an aneurysm 11 starts to expand and the aorta 12 is pulled and forced to curve away from its normal path, the grafts of the prior art 23 can become dislodged at end 24 (see Figure 4) or kink at a point 25 along their length, (as depicted in Figure 6).

The benefit of the present invention can be seen in the graft 10 is pre-curved to align with the aorta 12 which is pulled from its natural path due to the ballooning of an aneurysm 11. Further more, end 19 of the graft 10 is angled such that it still abuts against the walls of the aorta 12 when the aorta 12 is curved out by the pull of the aneurysm. In conventional grafts 23, as the aorta 12 is curved, the end 24 of the graft may not fit against the walls of the aorta 12 and the graft can have a tendency to dislodge as a result. This can be seen in Figures 4 and 5 where the section of aorta 12 proximal the renal arteries 17 and 18 deviates towards the expanding aneurysm such that an angle is formed. The angle may in some cases be up to 90° and thus the straight shaped conventional grafts 23 sometimes do not fit securely within the aorta 12, becoming dislodged.

Whilst the graft 10 is adapted to take on a pre-determined configuration such that it aligns with a non-linear vessel, the graft 10 may be inserted into a target vessel in a substantially straight configuration. Figure 8a and 8b depict one means of introducing a graft 10 into a vessel by way of a catheter 9. The graft 10

is forced into a substantially straight configuration within the catheter 9. The graft 10 is forced into a substantially straight configuration within the catheter 9. When positioned correctly within a target vessel, the graft 10 may be ejected from the catheter 9 by way of, for example, a push rod 30 whereupon the graft 10 takes on its pre-determined curved configuration (shown in Figure 8b).

In use, the shape of the vessel in to which the device is to be disposed may be imaged and the device chosen or specifically manufactured such that the shape of the graft 10 corresponds with the shape of the vessel. Imaging may be by way of ultrasound, plain abdominal films or by CT scanning. In this manner, the graft 10 is custom made such that it fits securely within the vessel.

It will be appreciated by persons skilled in the art that numerous variations, and /or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

What is claimed is:

1. In an intraluminal device comprising at least a tubular body having a length a first end and at least one second end, the improvement which comprises:

the tubular body being of a pre-determined non-linear shape.

2. The device as defined in claim 1, wherein said pre-determined shape corresponds with a shape of a non-linear shaped portion of a vessel to house the device.

3. The device as defined in claim 2, wherein the tubular body is curved along the length between the first and the at least one second end.

4. The device as defined in claim 3, where the tubular body further comprises a sigmoid curve disposed along its length between the first and the at least one second end.

5. The device as defined in claim 4, said at least a tubular body further comprising two pieces.

6. The device as defined in claim 4, said at least a tubular body further comprising three pieces.

7. The device as defined in claim 4, said at least a tubular body further comprising four pieces.

8. The device as defined in claim 3, further comprising a graft for bridging an aneurysm in an artery of a patient.

9. The device as defined in claim 3, further comprising a graft for bridging an aneurysm in an artery of a patient.

10. The device as defined in claim 3, further comprising a curvature along the length in an anterior-posterior plane.

11. The device as defined in claim 3, further comprising a curvature along the length in a lateral plane.

12. The device as defined in claim 3, further comprising a curvature along the length in both an anterior-posterior plane and a lateral plane.

13. The device as defined in claim 3, further comprising a unitary graft assembly angled by cutting to facilitate curvature of the tubular graft body.

14. The device as defined in claim 4, further comprising a unitary graft assembly angled by cutting to facilitate curvature of the tubular graft body.

15. The device as defined in claim 3, wherein a first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater that the reminder of the first end.

16. The device as defined in claim 4, wherein a first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater that the reminder of the first end.

17. The device as defined in claim 3, wherein the shape of the vessel or vessel portion in which the device is to be disposed is pre-determined and the device specifically manufactured such that the shape of the device corresponds with the shape of the vessel or vessel portion; and,
whereby the shape of the vessel is determined by at least one of ultrasound, plain abdominal films and CT scanning.

18. The device as defined in claim 4, wherein wherein the shape of the vessel or vessel portion in which the device is to be disposed is pre-determined and the device specifically manufactured such that the shape of the device corresponds with the shape of the vessel or vessel portion; and,
whereby the shape of the vessel is determined by at least one of ultrasound, plain abdominal films and CT scanning.

19. An intraluminal device comprising a tubular graft body having a length, a first end and at least one second end wherein the first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater that the remainder of the first end.

20. A method for emplacing an intraluminal device according, comprising the steps of:
introducing a catheter into an artery of a patient when the device body is in a radially compressed state;
causing the intraluminal device to be moved through the catheter until the intraluminal device extends into the vessel from a proximal end of the catheter or other delivery device;
allowing the intraluminal device to expand; and,
withdrawing the catheter or other delivery device along with any other apparatus used to introduce the intraluminal device into the vessel.

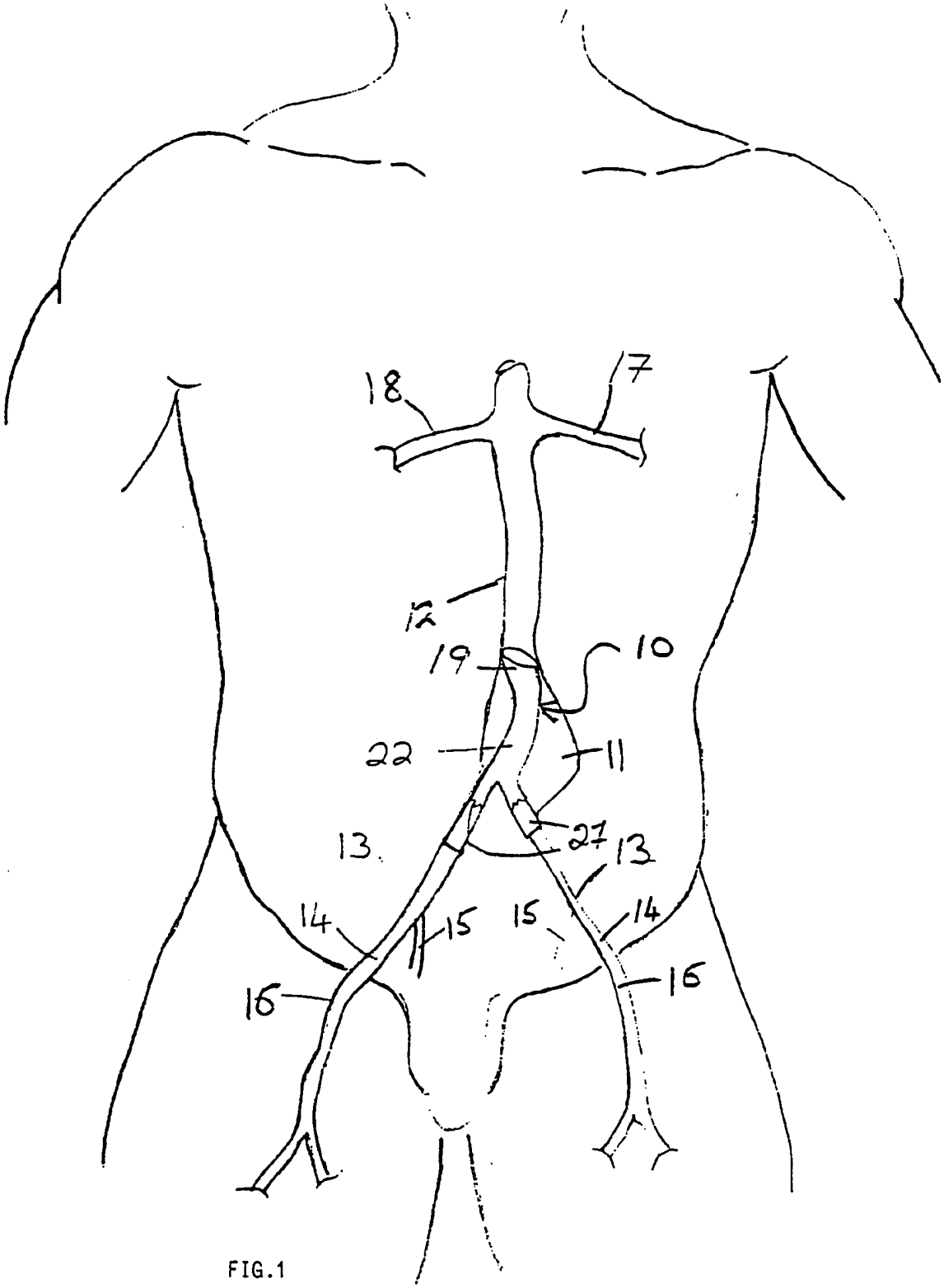

FIG.1

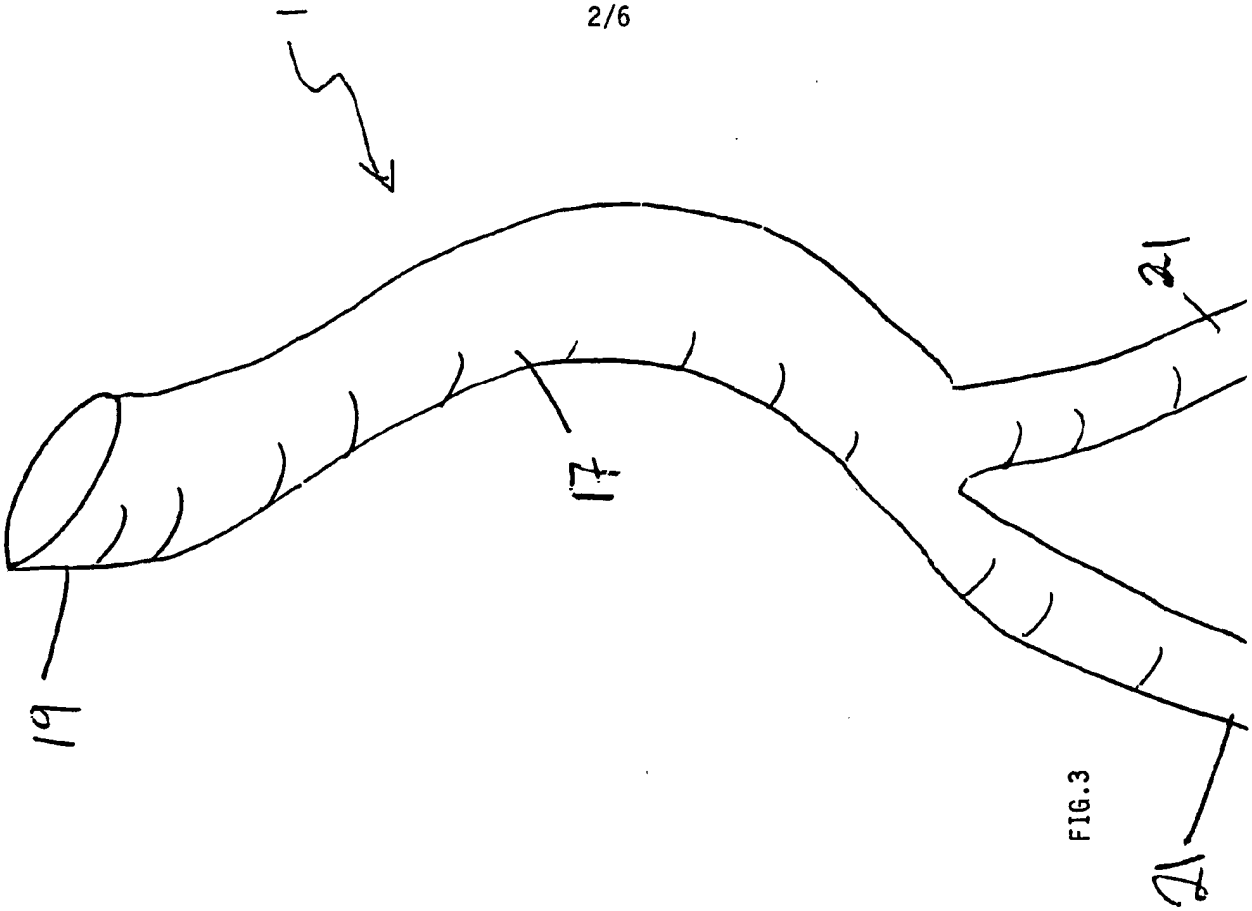

FIG.3

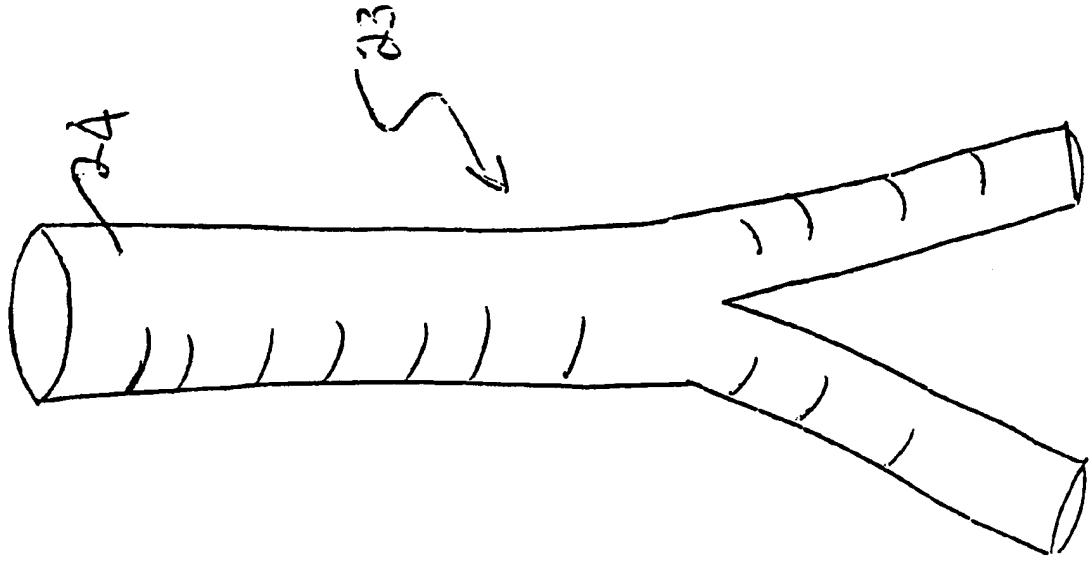

FIG.2

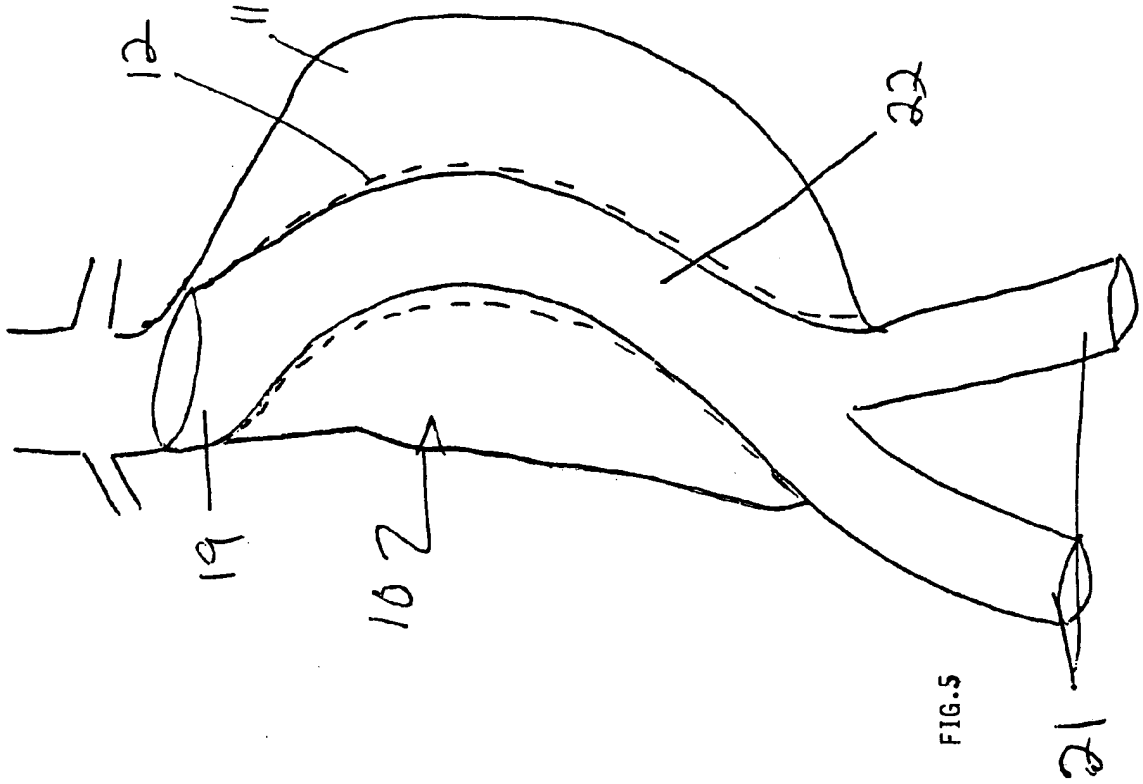

FIG.5

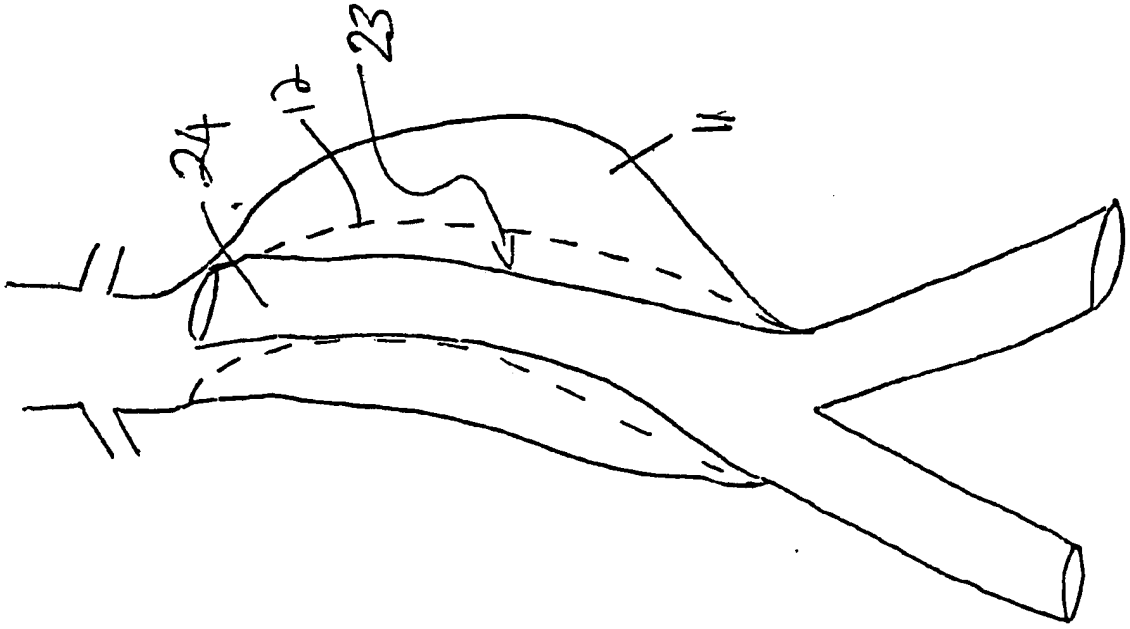

FIG.4

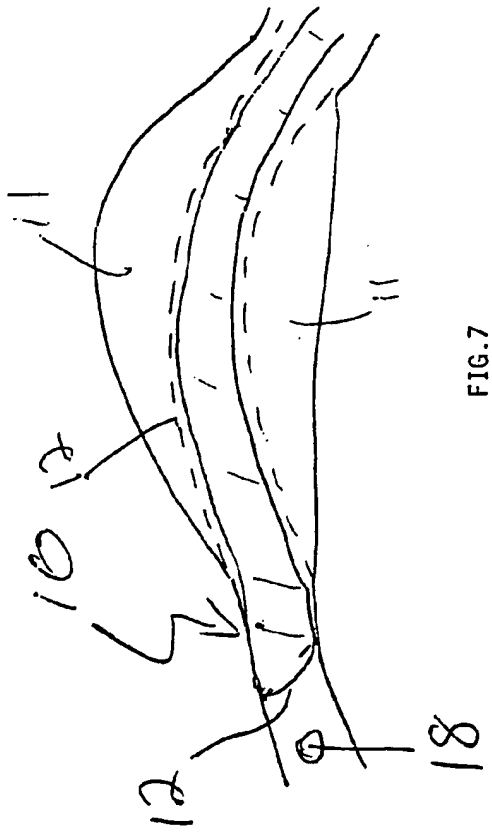

FIG.7

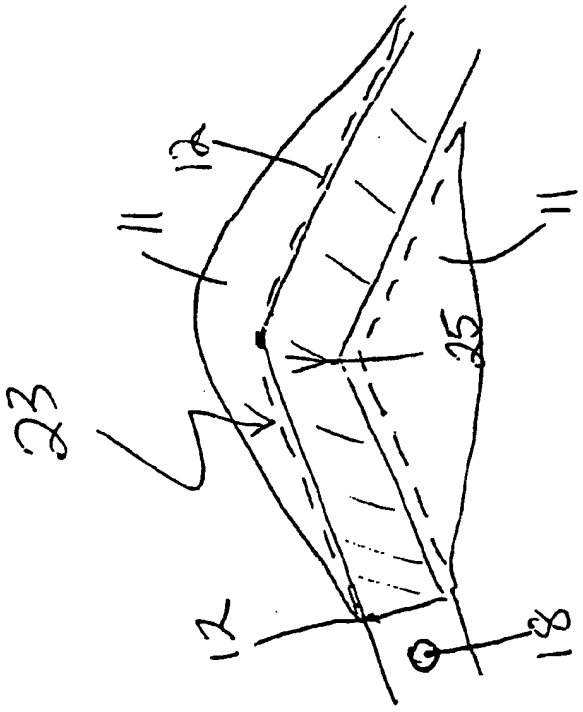

FIG.6

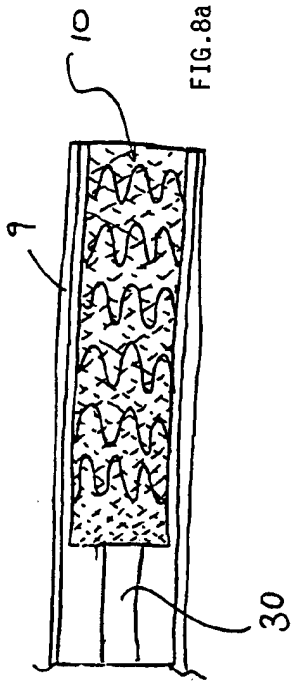

FIG.8a

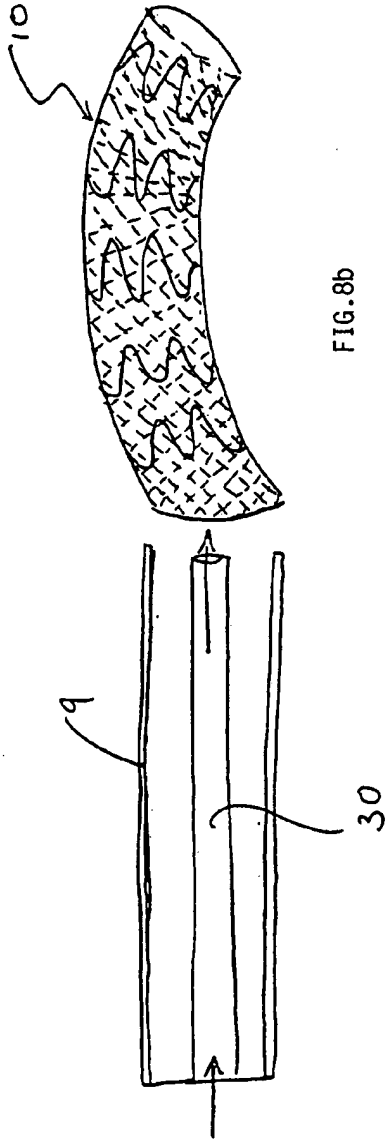

FIG.8b

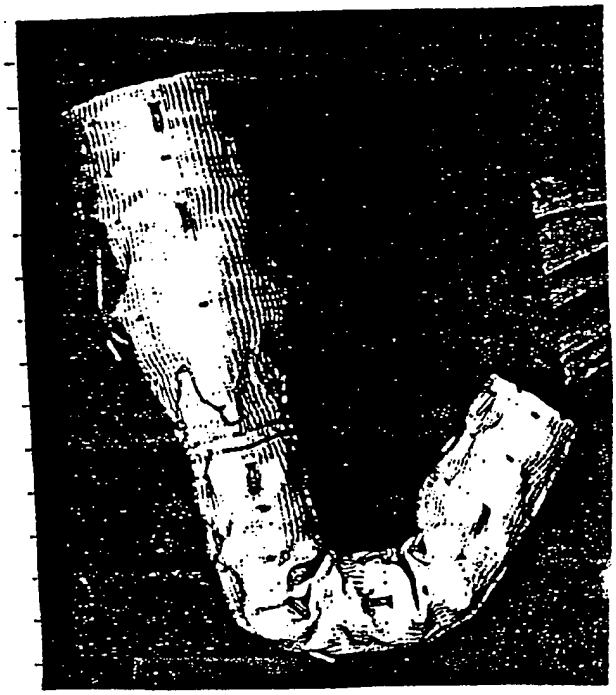

FIG.9

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 May 2001 (03.05.2001)

PCT

(10) International Publication Number
WO 01/30270 A3

(51) International Patent Classification[7]: A61F 2/06

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(22) International Filing Date:
25 September 2000 (25.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PQ 3029 23 September 1999 (23.09.1999) AU

(71) Applicants *(for all designated States except US)*: **EDWARDS LIFESCIENCES CORPORATION** [US/US]; One Edwards Way, Irvine, CA 92625 (US). **ENDOGAD RESEARCH PTY LIMITED** [AU/AU]; P.O. Box M88, Camperdown, NSW 2050 (AU).

(72) Inventors; and

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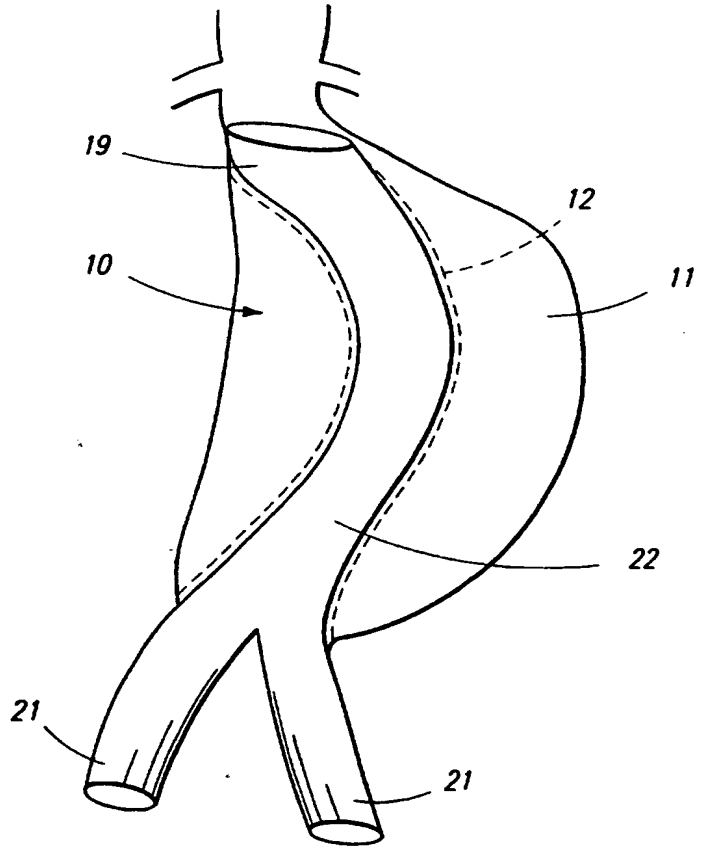
(74) Agents: **GLUCK, Peter, J.** et al.; Edwards Lifesciences LLC, One Edwards Way, Irvine, CA 92614 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

[Continued on next page]

(54) Title: PRE-SHAPED INTRALUMINAL GRAFT



(57) Abstract: An intraluminal graft having a predetermined substantially a linear configuration is ideally fitted within individuated aneurysmal regions, tortuous or primarily non-linear vessels, and a method of emplacing the same likewise discloses novel aspects.

WO 01/30270 A3

(84) **Designated States** *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(88) **Date of publication of the international search report:**
13 December 2001

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/26239

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 37242 A (ANSON MEDICAL LTD ;BEATON GAIL (GB); BUTCHER PETER (GB); MCLEOD AL) 29 July 1999 (1999-07-29) page 24, last paragraph -page 25, paragraph 1; claim 25; figures page 27, paragraph 2	1-3, 8-12,15, 19
A	---	4-7,13, 14,16
X	EP 0 808 614 A (SAMSUNG ELECTRONICS CO LTD) 26 November 1997 (1997-11-26) page 2, line 31 - line 45; figures	1-3,10
A	---	19
X	WO 99 32050 A (EMBOL X INC) 1 July 1999 (1999-07-01) figures 3,8-13	1,19
A	---	2,3
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 June 2001	12/06/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/26239

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 99 01073 A (MEDTRONIC INC) 14 January 1999 (1999-01-14) page 10, line 11 -page 11, line 32; figure 7 -----	17,18

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

ational Application No
PCT/US 00/26239

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9937242 A	29-07-1999	AU 2288699 A	09-08-1999
		BR 9907209 A	03-10-2000
		EP 1049420 A	08-11-2000
		GB 2349827 A	15-11-2000
EP 0808614 A	26-11-1997	KR 170220 B	20-03-1999
		KR 170219 B	20-03-1999
		CN 1170612 A	21-01-1998
		JP 10043315 A	17-02-1998
		US 6027525 A	22-02-2000
WO 9932050 A	01-07-1999	AU 1937499 A	12-07-1999
		EP 1041940 A	11-10-2000
WO 9901073 A	14-01-1999	US 6097978 A	01-08-2000

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
EDWI/P24490PC		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US00/26239	25/09/2000	23/09/1999

International Patent Classification (IPC) or national classification and IPC
A61F2/06

Applicant
EDWARDS LIFESCIENCES CORPORATION et al.

1. This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
19/04/2001	07.12.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Dhervé, G Telephone No. +49 89 2399 2415

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/26239

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-11 as originally filed

Claims, No.:

1-14 with telefax of 28/09/2001

Drawings, sheets:

1/6-6/6 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☒ the claims, Nos.: 15-20

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/26239

☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)
see separate sheet

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 4-6,14.

because:

☒ the said international application, or the said claims Nos. 14 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 4-6 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet

☒ the claims, or said claims Nos. 4-6 are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N) Yes: Claims 3,11-13

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/26239

	No:	Claims	1,2,7-10
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-3,7-13
Industrial applicability (IA)	Yes:	Claims	1-3,7-13
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

I. Basis of the report

The **amended dependent claims 4-6** filed with the letter dated 28.09.01 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. Nowhere in the originally filed disclosure it is made reference to additional "body elements" as at present defined in these claims.

According to Rule 70.2(c) PCT, the corresponding amendments were not considered for the establishment of the present report (see item III.2 below). Therefore, claims 4-6 were taking into account as if they contain the wording of the originally filed claims 4-6 ("further comprising two/three/four pieces").

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

III.1. No international preliminary examination is carried out on **claim 14**, as amended with the letter dated 28.09.01, because it relates to a method which involves an invasive treatment of the living body ("determining the shape of the vessel (...) by plain abdominal films or CT scanning") carried out under the responsibility of a doctor, and thus is covered by the provision of Article 34(4)(a)(i) PCT and Rule 67(1)(iv) PCT.

III.2. The features of **dependent claims 4-6** as interpreted (see the comments in Section I) are not referred to in the description. These claims are therefore not supported by the description as required by Article 5 PCT (see also the PCT Guidelines III-6.6). Furthermore, these claims do not meet the requirements of Article 6 PCT, because the intended structural limitations are not clear from the broad definitions "comprising two/three/four pieces" (pieces of what?)

V. Reasoned statement under Article 35(2) PCT with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: WO-A-99/37242
D2: WO-A-99/32050

V.1. Independent claim 1

The document D1 discloses (see, in particular, the embodiment of figure 8, page 24, last paragraph, page 25, two first paragraphs, but also figures 15, 16 and page 27, second paragraph) an intraluminal device comprising a radially compressible tubular body having a length, a first end and at least one second end wherein the tubular body has a pre-formed pre-determined non linear shape prior to insertion into a vessel.

It is to be noted that document D2 also shows a device as defined above (see figures 12 and 13 which clearly show a non linear shape. In order to get this shape once the device delivered by the delivery cannula, it has obviously been previously pre-stressed in the desired curved shape).

Thus, the subject-matter of **independent claim 1** is not novel in the sense of Article 33(2) PCT.

V.2. Dependent claims 2, 3 and 7-13

Dependent claims 2 and 7-10 (for claims 7, 8, 9 and 10, see also the objections raised in Section VIII) do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Article 33(2) PCT), document D1 showing:

- a tubular body curved along its length (see figure 8) as defined in claims 2, 9 and 10;
- a graft as claimed in claim 7 or 8 (see the abstract).

Dependent claims 3 and 11-13 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT), because they merely define slight constructional change in the device of claim 1 which come within the scope of the customary practice followed by persons skilled in the art and do not appear to provide any surprising technical effect which could justify an inventive step.

VII. Certain defects in the international application

VII.1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

VII.2. Contrary to the requirements of Rule 6.2(b) PCT, the features of the claims are not provided with reference signs placed in parentheses (see also the PCT Guidelines III-4.11).

VII.3. The term "Dacron" used on page 8, line 29 and on page 9, line 2, is a registered trade mark and should have been identified as such (see the PCT Guidelines, II-4.16 and III-4.5b).

VII.4. The mention "which is expressly incorporated herein by reference" on page 2, line 2, should have been deleted. If the referred documents are useful for understanding the claimed invention, a brief summary of their contents should have been included in the description (see the PCT Guidelines, II-4.17).

VII.5. Minor defects:

- On figure 1, the reference sign "27" should have been corrected into "21";
- On figure 3, the reference sign "17" should have been corrected into "22";
- Page 11, lines 1 and 2, the sentence "the graft 10 is forced (...) within the catheter" is a repetition of the previous sentence and therefore should have been deleted.

VIII. Certain observations on the international application

VIII.1. The content of **dependent claim 7** is identical to the content of **dependent claim 8**. For conciseness reason (Article 6 PCT) one of these two claims should have been deleted.

VIII.2. In **dependent claims 9 and 10**, the expressions "in an anterior-posterior plane"

and "in a lateral plane", respectively, are relative since they relate to the use of the device and, therefore, depend on in-situ location references (see also the description page 3, lines 15-20). Lack of conciseness arises (Article 6 PCT) because the above cited claims do not appear to define additional technical features that are not already defined in **dependent claim 2.**

VIII.3. The vague and imprecise statement in the description on page 11, last paragraph, especially the mention to "the spirit of the invention", implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, III-4.3a).

The demand must be filed directly with the competent International Preliminary Examining Authority or, if two or more Authorities are competent, with the one chosen by the applicant. The full name or two-letter code of that Authority must be indicated by the applicant on the line below:

IPEA/_____

PCT

CHAPTER II

DEMAND

under Article 31 of the Patent Cooperation Treaty:
The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA	Date of receipt of DEMAND

Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION

Applicant's or agent's file reference: EDWI/P24490PC

International application No.	International filing date *(day/month/year)*	(Earliest) Priority date *(day/month/year)*
PCT/US00/26239		23/09/1999

Title of invention: PRE-SHAPED INTRALUMINAL GRAFT

Box No. II APPLICANT(S)

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State *(that is, country)* of residence: AU

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United States of America

State *(that is, country)* of nationality: US
State *(that is, country)* of residence: US

[X] Further applicants are indicated on a continuation sheet.

Sheet No. 2

International application No.
PCT/US00/26239

Continuation of Box No. II APPLICANT(S)

If none of the following sub-boxes is used, this sheet should not be included in the demand.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

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AU	AU

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

State *(that is, country)* of nationality:	State *(that is, country)* of residence:

☐ Further applicants are indicated on a continuation sheet.

International application No.
PCT/US00/26239

Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The following person is [X] agent [ ] common representative

and [ ] has been appointed earlier and represents the applicant(s) also for international preliminary examination.

[ ] is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.

[X] is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: *(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)*

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Eric Potter Clarkson
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Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION

Statement concerning amendments:*

1. The applicant wishes the international preliminary examination to start on the basis of:

[X] the international application as originally filed

the description [ ] as originally filed
[ ] as amended under Article 34

the claims [ ] as originally filed
[ ] as amended under Article 19 (together with any accompanying statement)
[ ] as amended under Article 34

the drawings [ ] as originally filed
[ ] as amended under Article 34

2 [ ] The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3. [ ] The applicant wishes the start of the international preliminary examination **to be postponed** until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). *(This check-box may be marked only where the time limit under Article 19 has not yet expired.)*

* Where no checkbox is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: English

[X] which is the language in which the international application was filed

[ ] which is the language of a translation furnished for the purposes of international search

[ ] which is the language of publication of the international application

[ ] which is the language of the translation (to be) furnished for the purposes of international preliminary examination

Box No. V ELECTION OF STATES

The applicant hereby **elects all eligible States** *(that is, all States which have been designated and which are bound by Chapter II of the PCT)*

excluding the following States which the applicant wishes **not to elect:**

Sheet No. 4

International application No. PCT/US00/26239

Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:				For International Preliminary Examining Authority use only: received	For International Preliminary Examining Authority use only: not received
1. translation of international application	:	0	sheets	☐	☐
2. amendments under Article 34	:	0	sheets	☐	☐
3. copy (or, where required, translation) of amendments under Article 19	:	0	sheets	☐	☐
4. copy (or, where required, translation) of statement under Article 19	:	0	sheets	☐	☐
5. letter	:	0	sheets	☐	☐
6. other *(specify)*	:	0	sheets	☐	☐

The demand is also accompanied by the item(s) marked below:

1. [X] fee calculation sheet
2. [ ] separate signed power of attorney
3. [X] copy of general power of attorney; reference number, if any:
4. [ ] statement explaining lack of signature
5. [ ] nucleotide and or amino acid sequence listing in computer readable form
6. [ ] other *(specify)*:

BOX NO. IV SIGNATURE, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand)

Colin J. Baker

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:
2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):
3. [ ] The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply. [ ] The applicant has been informed accordingly.
4. [ ] The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.
5. [ ] Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

For International Bureau use only

Demand received from IPEA on:

CHAPTER II

PCT

FEE CALCULATION SHEET

Annex to the Demand for international preliminary examination

International application No.	PCT/US00/26239
Applicant's or agent's file reference	EDWI/P24490PC

For International Preliminary Examining Authority use only

Date stamp of the IPEA

Applicant: Edwards Lifesciences Corporation, et al

Calculation of prescribed fees

1. Preliminary examination fee	1533.00 (EURO) P	
2. Handling fee *(Applicants from certain States are entitled to a reduction of 75% of the handling fee. Where the applicant is (or all applicants are) so entitled, the amount to be entered at H is 25% of the handling fee.)*	148.00 (EURO) H	
3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box	1681.00 (EURO) TOTAL	

Mode of Payment

- ☐ authorization to charge deposit account with the IPEA (see below)
- ☐ cheque
- ☐ Postal money order
- ☐ bank draft
- ☐ cash
- ☐ revenue
- ☐ coupons
- ☐ other *(specify)*:

Deposit Account Authorization *(this mode of payment may not be available at all IPEAs)*

The IPEA/ _____

- ☐ is hereby authorized to charge the total fees indicated above to my deposit account.
- ☐ *(this check-box may be marked only if the conditions for deposit accounts of the IPEA so permit)* is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.

Deposit Account Number _____ Date *(day/month/year)* _____ Signature _____

See Notes to the fee calculation sheet

PATENT CO-OPERATION TREATY

APPOINTMENT OF AGENT

The undersigned Applicant(s)

Edwards Lifesciences Corporation

hereby appoint(s) as Agents:

C.J.Baker, R.S.Bassett, I.A.Buchan, R.J.Charig, P.Coxon, B.Dealtry I.M.Dee, N.V.H. Fox-Male, M.J.Gilding, C.Goodman, G.MacGregor, S.P.McNeeney J.S.Miles, T.J.Powell, J.Singleton, S.Snelgrove, I.E.Stevens, W.Strasser, P.J.D.Thomas

of ERIC POTTER CLARKSON

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to act on his (her, their) behalf before the competent International Authorities in connection with any International applications filed with the United Kingdom Patent Office as receiving Office and to make or receive payments on his (her, their) behalf.

Place: Irvine, California USA Date: Oct 16, 2000

Signature(s) _____

Bruce P. Garren
Corporate Vice President,
General Counsel & Secretary

Name (and capacity)

For and on behalf of
Edwards Lifesciences Corporation

ECV-5476

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European Patent Office
Directorate General 2
Erhardtstrasse 27
D-80298 München
GERMANY

w/letter dated 9/28/01

28 September 2001

Sent by fax

Dear Sirs

International Application No. PCT/US00/26239
EDWARDS LIFESCIENCES LLC
Our ref: P24490PC

This is in response to the Written Opinion dated 31 July 2001.

We enclose herewith manuscript amended replacement pages 12, 13 and 14.

In the claims, Claim 1 has been amended to define clearly the subject matter for which protection is sought. Previous Claims 2, 17 and 18 have been replaced by new Claim 14. Previous claims 19 and 20 have been deleted. Claims 5 to 7 have been amended to make them clear.

The basis for the amendments to new Claim 1 can be found at page 4, lines 26 to 27; page 9, line 11; and page 8, line 26 to page 9, line 2 in conjunction with Figure 9. None of the amendments to the claims constitutes added subject matter.

Turning now to the issues of novelty and inventive step, amended Claim 1 filed herewith defines an intraluminal device which is radially compressible and which is manufactured to be non-linear in shape prior to its insertion into a vessel, eg. an artery or a vein. WO99/37242(D1) discloses linear grafts which have, in particular, a rigid cylindrical shape (see page 20, line 14). The problem addressed by D1 is to prevent occlusion of the graft when it is in a

cont/....

bent configuration within the body. This problem is addressed in D1 by the provision of a specific stent or wire form support for the graft body. The examiner refers explicitly to Figure 8 of D1, but this simply shows how the stent or wire form prevents occlusion of the graft upon bending, i.e. it shows how the graft bends when inserted into a vessel. There is no disclosure or teaching in D1 of a graft which has a non-linear configuration at rest prior to insertion and which has a pre-determined non-linear shape. Accordingly, the subject matter of the amended claims filed herewith satisfies the requirements for novelty and inventive step in respect of D1.

WO99/32050(D2) on the other hand discloses a device for diverting embolic material away from the arteries that carry blood to the brain. This document specifically discloses and teaches that the devices should include a hollow tube which is substantially cylindrical or conical (see page 12, line 25), i.e. linear in shape in that they include a linear central axis. The device only becomes non-linear after implantation into the aorta. Accordingly, there is no disclosure or teaching in D2 of an intraluminal device which is pre-formed to have a non-linear shape prior to insertion into a vessel. Therefore, the subject matter of the amended claims filed herewith is both novel and inventive in respect of this document.

The final document relied upon by the examiner is US 5,180,362(D3). However, this document discloses and teaches a helical steel tube. This tube is clearly not radially compressible for intraluminal insertion. In fact, it is inserted using a hollow needle, sized to receive therein the steel tube. There is no disclosure or suggestion of the steel tube being radially compressible and, therefore, the subject matter of the amended claims filed herewith is both novel and inventive over this document.

With regard to the issues raised by the examiner in connection with the description part of the specification, the applicant intends to address these points once acknowledgement has been received that the claims are allowable.

Any amendment is not to be construed as abandonment of subject matter.

cont/....

In view of the above, the examiner should be able to issue an IPER which is positive at least in terms of novelty and inventive step. However, if the examiner feels unable to issue such a positive IPER, then a further Written Opinion is requested so that the outstanding issues may be addressed.

Yours faithfully
ERIC POTTER CLARKSON

Andrew Bridle jh

Enc: Manuscript pages 12-14

What is claimed is:

1. An intraluminal device comprising ~~at least~~ a radially compressible tubular body having a length a first end and at least one second end, ~~the improvement which comprises:~~

wherein the tubular body has a pre-formed ~~being of a~~ pre-determined non-linear shape prior to insertion into a vessel.

2. The device as defined in claim 1, wherein said pre-determined shape corresponds with a shape of a non-linear shaped portion of a vessel to house the device.

3. The device as defined in claim 1, wherein the tubular body is curved along the length between the first and the at least one second end.

4. The device as defined in claim 2, where the tubular body further comprises a sigmoid curve disposed along its length between the first and the at least one second end.

5. The device as defined in claim 3, ~~said at least a~~ wherein the tubular body ~~further comprising two pieces.~~ comprises two body elements.

6. The device as defined in claim 4, ~~said at least a~~ wherein the tubular body ~~further comprising three pieces.~~ comprises three body elements.

7. The device as defined in claim 3, ~~said at least a~~ wherein the tubular body ~~further comprising four pieces.~~ comprises four body elements.

8. The device as defined in claim 2, further comprising a graft for bridging an aneurysm in an artery of a patient.

8 9. The device as defined in claim 2 1, further comprising a graft for bridging an aneurysm in an artery of a patient.

9 10. The device as defined in claim 2 1, further comprising a curvature along the length in an anterior-posterior plane.

10 11. The device as defined in claim 2 1, further comprising a curvature along the length in a lateral plane.

11 12. The device as defined in claim 2 1, further comprising a curvature along the length in both an anterior-posterior plane and a lateral plane.

12 2 or 3 13. The device as defined in claim 1, further comprising a unitary graft assembly angled by cutting to facilitate curvature of the tubular graft body.

14. The device as defined in claim 4, further comprising a unitary graft assembly angled by cutting to facilitate curvature of the tubular graft body.

13 2 or 3 15. The device as defined in claim 1, wherein a first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater that the reminder of the first end.

16. The device as defined in claim 4, wherein a first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater that the reminder of the first end.

17. The device as defined in claim 3, wherein the shape of the vessel or vessel portion in which the device is to be disposed is pre-determined and the device specifically manufactured such that the shape of the device corresponds with the shape of the vessel or vessel portion; and,
whereby the shape of the vessel is determined by at least one of ultrasound, plain abdominal films and CT scanning.

18. The device as defined in claim 4, wherein wherein the shape of the vessel or vessel portion in which the device is to be disposed is pre-determined and the device specifically manufactured such that the shape of the device corresponds with the shape of the vessel or vessel portion; and,
whereby the shape of the vessel is determined by at least one of ultrasound, plain abdominal films and CT scanning.

19. An intraluminal device comprising a tubular graft body having a length, a first end and at least one second end wherein the first end of the tubular body is angled such that when viewed in a vertical cross-sectional plane, a portion of the tubular body extends outwardly longitudinally a distance greater that the remainder of the first end.

20. A method for emplacing an intraluminal device according, comprising the steps of :
introducing a catheter into an artery of a patient when the device body is in a radially compressed state;
causing the intraluminal device to be moved through the catheter until the intraluminal device extends into the vessel from a proximal end of the catheter or other delivery device;
allowing the intraluminal device to expand; and,
withdrawing the catheter or other delivery device along with any other apparatus used to introduce the intraluminal device into the vessel.

14. A method of preparing a device according to any preceding claim including the steps :
(i) determining the shape of the vessel or vessel portion in which the device is to be disposed by at least one of ultrasound, plain abdominal films or CT scanning ; and
(ii) manufacturing the device such that the shape of the device corresponds with the shape of the vessel or vessel portion.